AMENDMENT TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 4250 OFFERED BY MR. DINGELL OF MICHIGAN

Page 2, line 12, after ''misbranded'' insert ''for use under the conditions prescribed, recommended, or suggested in the product's labeling, as described in section 201(p)''.

Page 2, line 17, strike ''review of a nonprescription sunscreen active ingredient for a GRASE determination'' and insert ''consideration for inclusion in the over-the-counter drug monograph system''.

Page 7, lines 20 to 22, strike ''is complete'' and insert ''is sufficiently complete to conduct a substantive review''.

Page 8, line 2, strike ''inadequate to make a GRASE determination'' and insert ''not sufficiently complete to conduct a substantive review''.

Page 8, line 22, strike ''insists'' and insert ''asks''.

Page 8, beginning at line 5, amend paragraph (3) to read as follows:

''(3) the Secretary shall, in filing a request under paragraph (2)—

''(A) invite the public to submit further comments with respect to such filing; and

''(B) limit such public comment, and the comment period under paragraph (1), to the period ending on the date that is 60 days after such filing;

Page 8, line 16, strike ''an informal conference'' each place it appears and insert ''a meeting''.

Page 8, lines 19 and 20, strike ''the informal conference'' and insert ''the meeting''.

Page 8, line 21, strike ''such informal conference'' and insert ''such meeting''.

Page 9, line 12, strike ''insufficient to make a GRASE determination'' and insert ''not sufficiently complete to conduct a substantive review''.

Page 16, lines 13 to 22, amend paragraph (7) to read as follows:

''(7) ADVISORY COMMITTEE.—For a proposed order issued under paragraph (3)(A)(iii) or (5)(C) requesting additional information, an Advisory Committee meeting shall be convened if the sponsor re-

quests, or the Director of the Center for Drug Evaluation and Research or the Commissioner of Food and Drugs decides, to convene such a meeting for the purpose of reviewing the pending request.

Page 18, lines 13 through 24, amend paragraph (1) to read as follows:

''(1) LIMITATIONS.—The Food and Drug Administration—

''(A) shall not be required to convene the Advisory Committee—

''(i) more than once with respect to any request under section 586A(a) or any pending request; or

''(ii) more than twice in any twelve month period with respect to the review of submissions under this section; and

''(B) shall not be required to submit more than 3 submissions to the Advisory Committee per meeting.

Page 20, line 6, after ''interstate commerce'' insert '', for use under the conditions subject to the final order,''.

Page 20, line 16, after ''interstate commerce'' insert '', for use under the conditions subject to the final order,''.

Page 25, line 21, after ''safety'' insert ''and efficacy''.

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